

FIRST REGULAR SESSION

# HOUSE BILL NO. 816

## 98TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE ENGLER.

1926H.011

D. ADAM CRUMBLISS, Chief Clerk

### AN ACT

To repeal section 195.015 as enacted by senate bill nos. 215 & 58, eighty-fifth general assembly, first regular session, and to enact in lieu thereof ten new sections relating to a prescription drug monitoring program, with penalty provisions and a referendum clause.

*Be it enacted by the General Assembly of the state of Missouri, as follows:*

Section A. Section 195.015 as enacted by senate bill nos. 215 & 58, eighty-fifth general assembly, first regular session, are repealed and ten new sections enacted in lieu thereof, to be known as sections 195.015, 195.450, 195.453, 195.456, 195.459, 195.462, 195.465, 195.468, 195.471, and 195.475, to read as follows:

195.015. 1. The department of health and senior services shall administer sections 195.005 to [195.425] **195.475** and may add substances to the schedules after public notice and hearing. In making a determination regarding a substance, the department of health and senior services shall consider the following:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the substance;
- (4) The history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) The risk to the public health;
- (7) The potential of the substance to produce psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under sections 195.005 to [195.425] **195.475**.

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

15           2. After considering the factors enumerated in subsection 1 of this section the department  
16 of health and senior services shall make findings with respect thereto and issue a rule controlling  
17 the substance if it finds the substance has a potential for abuse.

18           3. If the department of health and senior services designates a substance as an immediate  
19 precursor, substances which are precursors of the controlled precursor shall not be subject to  
20 control solely because they are precursors of the controlled precursor.

21           4. If any substance is designated, rescheduled, or deleted as a controlled substance under  
22 federal law and notice thereof is given to the department of health and senior services, the  
23 department of health and senior services shall similarly control the substance under sections  
24 195.005 to [195.425] **195.475** after the expiration of thirty days from publication in the federal  
25 register of a final order designating a substance as a controlled substance or rescheduling or  
26 deleting a substance, unless within that thirty-day period, the department of health and senior  
27 services objects to inclusion, rescheduling, or deletion. In that case, the department of health and  
28 senior services shall publish the reasons for objection and afford all interested parties an  
29 opportunity to be heard. At the conclusion of the hearing, the department of health and senior  
30 services shall publish its decision, which shall be final unless altered by statute. Upon  
31 publication of objection to inclusion, rescheduling or deletion under sections 195.005 to  
32 [195.425] **195.475** by the department of health and senior services, control under sections  
33 195.005 to [195.425] **195.475** is stayed as to the substance in question until the department of  
34 health and senior services publishes its decision.

35           5. The department of health and senior services shall exclude any nonnarcotic substance  
36 from a schedule if such substance may, under the federal Food, Drug, and Cosmetic Act and the  
37 law of this state, be lawfully sold over the counter without a prescription.

38           6. The department of health and senior services shall prepare a list of all drugs falling  
39 within the purview of controlled substances. Upon preparation, a copy of the list shall be filed  
40 in the office of the secretary of state.

**195.450. 1. Sections 195.450 to 195.475 shall be known and may be cited as the**  
2 **"Prescription Drug Monitoring Program Act".**

3           **2. As used in sections 195.450 to 195.475, the following terms mean:**

4           **(1) "Controlled substance", the same meaning given such term in section 195.010;**

5           **(2) "Department", the department of health and senior services;**

6           **(3) "Dispenser", a person who delivers a Schedule II, III, or IV controlled**  
7 **substance to the ultimate user, but does not include:**

8           **(a) A hospital, as defined in section 197.020, that distributes such substances for the**  
9 **purpose of inpatient care or dispenses prescriptions for controlled substances at the time**  
10 **of discharge at such facility;**

- 11           (b) A practitioner or other authorized person who administers such a substance;  
12 or  
13           (c) A wholesale distributor of a Schedule II, III, or IV controlled substance;  
14           (4) "Patient", a person who is the ultimate user of a drug for whom a prescription  
15 is issued or for whom a drug is dispensed, except that patient shall not include a hospice  
16 patient enrolled in a Medicare-certified hospice program who has controlled substances  
17 dispensed to him or her by such hospice program;  
18           (5) "Schedule II, III, or IV controlled substance", a controlled substance that is  
19 listed in Schedule II, III, or IV of the schedules provided under this chapter or the Federal  
20 Controlled Substances Act, 21 U.S.C. Section 812.

21           3. Notwithstanding any other law to the contrary, the provisions of this section shall  
22 not apply to persons licensed under chapter 340.

          195.453. 1. The department of health and senior services shall establish and  
2 maintain a program for the monitoring of prescribing and dispensing of all Schedule II,  
3 III, and IV controlled substances by all professionals licensed to prescribe or dispense such  
4 substances in this state. The department may apply for any available grants and shall  
5 accept any gifts, grants, or donations to develop and maintain the program. All funding  
6 for the prescription drug monitoring program shall be provided exclusively by gifts,  
7 grants, and donations.

8           2. Each dispenser shall submit to the department by electronic means information  
9 regarding each dispensation of a drug included in subsection 1 of this section. The  
10 information submitted for each dispensation shall include, but not be limited to:

- 11           (1) The pharmacy federal Drug Enforcement Administration (DEA) number;  
12           (2) The date of the dispensation;  
13           (3) If there is a prescription:  
14           (a) The prescription number;  
15           (b) Whether the prescription is new or a refill;  
16           (c) The prescriber DEA or National Provider Identifier (NPI) number;  
17           (d) The date the prescription is issued by the prescriber; and  
18           (e) The source of payment for the prescription;  
19           (4) The National Drug Code (NDC) for the drug dispensed;  
20           (5) The number of days' supply of the drug;  
21           (6) The quantity dispensed;  
22           (7) The patient identification number including, but not limited to, any one of the  
23 following:  
24           (a) The patient's driver's license number;

- 25           (b) The patient's government-issued identification number; or  
26           (c) The patient's insurance cardholder identification number;  
27           (8) The patient's name, address, and date of birth.

28           3. Each dispenser shall submit the information in accordance with transmission  
29 standards established by the American Society for Automation in Pharmacy, or any  
30 successor organization, and shall report data within seven days.

31           4. (1) The department may issue a waiver to a dispenser who is unable to submit  
32 dispensation information by electronic means. Such waiver may permit the dispenser to  
33 submit dispensation information by paper form or other means, provided all information  
34 required in subsection 2 of this section is submitted in such alternative format.

35           (2) The department may grant an extension to dispensers who are temporarily  
36 unable to electronically submit the dispensation information required in subsection 2 of  
37 this section in accordance with the time frame established in subsection 3 of this section  
38 due to unforeseen circumstances. If an extension is granted, dispensers shall be responsible  
39 for reporting the required data in a subsequent file.

40           5. The department shall reimburse each dispenser for the fees and other direct costs  
41 of transmitting the information required by this section.

          195.456. 1. Dispensation information submitted to the department shall be  
2 confidential and not subject to public disclosure under chapter 610 except as provided in  
3 subsections 3 to 5 of this section.

4           2. The department shall maintain procedures to ensure that the privacy and  
5 confidentiality of patients and personal information collected, recorded, transmitted, and  
6 maintained is not disclosed to persons except as provided in subsections 3 to 5 of this  
7 section.

8           3. The department shall review the dispensation information and, if there is  
9 reasonable cause to believe a violation of law or breach of professional standards may have  
10 occurred, the department shall notify the appropriate law enforcement or professional  
11 licensing, certification, or regulatory agency or entity, and provide dispensation  
12 information required for an investigation.

13           4. The department may provide data in the controlled substances dispensation  
14 monitoring program to the following persons:

15           (1) Persons, both in-state and out-of-state, authorized to prescribe or dispense  
16 controlled substances for the purpose of providing medical or pharmaceutical care for  
17 their patients;

18           (2) An individual who requests his or her own dispensation monitoring information  
19 in accordance with state law;

20           (3) The state board of pharmacy;

21           (4) Any state board charged with regulating a professional who has the authority  
22 to prescribe or dispense controlled substances that requests data related to a specific  
23 professional under the authority of that board;

24           (5) Local, state, and federal law enforcement or prosecutorial officials, both in-state  
25 and out-of-state engaged in the administration, investigation, or enforcement of the laws  
26 governing licit drugs based on a specific case and under a subpoena or court order;

27           (6) The family support division within the department of social services regarding  
28 MO HealthNet program recipients;

29           (7) A judge or other judicial authority under a subpoena or court order; and

30           (8) Personnel of the department of health and senior services for the administration  
31 and enforcement of sections 195.450 to 195.475.

32           5. The department may provide data to public or private entities for statistical,  
33 research, or educational purposes after removing information that could be used to identify  
34 individual patients, prescribers, dispensers, or persons who received dispensations from  
35 dispensers.

36           6. Nothing in sections 195.450 to 195.475 shall be construed to require a pharmacist  
37 or prescriber to obtain information about a patient from the database. A pharmacist or  
38 prescriber shall not be held liable for damages to any person in any civil action for injury,  
39 death, or loss to person or property on the basis that the pharmacist or prescriber did or  
40 did not seek or obtain information from the database.

          195.459. The department is authorized to contract with any other agency of this  
2 state or any other state, with a private vendor, or any state government that currently runs  
3 a prescription monitoring program. Any contractor shall comply with the provisions  
4 regarding confidentiality of prescription information in section 195.456.

          195.462. The department shall promulgate rules setting forth the procedures and  
2 methods of implementing sections 195.450 to 195.475. Any rule or portion of a rule, as that  
3 term is defined in section 536.010, that is created under the authority delegated in this  
4 section shall become effective only if it complies with and is subject to all of the provisions  
5 of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are  
6 nonseverable, and if any of the powers vested with the general assembly pursuant to  
7 chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are  
8 subsequently held unconstitutional, then the grant of rulemaking authority and any rule  
9 proposed or adopted after August 28, 2015, shall be invalid and void.

          195.465. 1. A dispenser who knowingly fails to submit dispensation monitoring  
2 information to the department as required in sections 195.450 to 195.475 or knowingly

3 submits the incorrect dispensation information shall be subject to an administrative  
4 penalty in the amount of one thousand dollars for each violation. The penalty shall be  
5 assessed through an order issued by the director of the department. Any person subject  
6 to an administrative penalty may appeal to the administrative hearing commission under  
7 the provisions of chapter 621.

8       2. A person authorized to have dispensation monitoring information under sections  
9 195.450 to 195.475 who knowingly discloses such information in violation of sections  
10 195.450 to 195.475 or who uses such information in a manner and for a purpose in  
11 violation of sections 195.450 to 195.475 is guilty of a class A misdemeanor.

195.468. 1. The department shall create and implement the following education  
2 courses:

3       (1) An orientation course during the implementation phase of the dispensation  
4 monitoring program established in section 195.453;

5       (2) A course for persons who are authorized to access the dispensation monitoring  
6 information but who did not participate in the orientation course;

7       (3) A course for persons who are authorized to access the dispensation monitoring  
8 information but who have violated laws or breached occupational standards involving  
9 dispensing, prescribing, or using substances monitored by the dispensation monitoring  
10 program established in section 195.453.

11

12 When appropriate, the department shall develop the content of the education courses  
13 described in subdivisions (1) to (3) of this subsection.

14       2. The department shall, when appropriate:

15       (1) Work with associations for impaired professionals to ensure intervention,  
16 treatment, and ongoing monitoring and followup; and

17       (2) Encourage individual patients who are identified and who have become  
18 addicted to substances monitored by the dispensation monitoring program established in  
19 section 195.453 to receive addiction treatment.

195.471. Under section 23.253 of the Missouri sunset act:

2       (1) The provisions of the new program authorized under sections 195.450 to  
3 195.471 shall automatically sunset six years after the effective date of sections 195.450 to  
4 195.471 unless reauthorized by an act of the general assembly;

5       (2) If such program is reauthorized, the program authorized under sections 195.450  
6 to 195.471 shall automatically sunset six years after the effective date of the reauthorization  
7 of sections 195.450 to 195.471; and

8           **(3) Sections 195.450 to 195.471 shall terminate on September first of the calendar**  
9 **year immediately following the calendar year in which the program authorized under**  
10 **sections 195.450 to 195.471 is sunset.**

**195.475. 1. By no later than January 1, 2017, the bureau of narcotics and**  
2 **dangerous drugs within the department of health and senior services shall establish a two-**  
3 **year statewide pilot project for the reporting of fraudulently obtained prescription**  
4 **controlled substances. The pilot project shall include the following:**

5           **(1) Provide a toll-free number for reporting to the bureau by physicians,**  
6 **pharmacists, and other health care professionals with prescriptive authority who have**  
7 **reason to believe that a person is fraudulently attempting to obtain a prescription for a**  
8 **controlled substance or is attempting to obtain an excessive amount of a controlled**  
9 **substance by prescription;**

10          **(2) Establish a system within the bureau for receiving such reports under**  
11 **subdivision (1) of this subsection along with any evidence offered or submitted by the**  
12 **reporter which indicates the fraud; and**

13          **(3) Forward such reports, along with any evidence offered or submitted to the**  
14 **appropriate prosecuting attorney or the state attorney general for investigation and**  
15 **prosecution.**

16          **2. On or before February 1, 2017, and February 1, 2018, the bureau of narcotics**  
17 **and dangerous drugs shall submit a report to the general assembly detailing the following**  
18 **specifics regarding the pilot project:**

19           **(1) The number of reports received under this section;**

20           **(2) The type of evidence offered or submitted indicating the fraud;**

21           **(3) The number of referrals to the attorney general and each local prosecuting**  
22 **attorney;**

23           **(4) The number of cases investigated and prosecuted as a result of such reporting,**  
24 **and the number of convictions or pleas resulting from such investigations and**  
25 **prosecutions. The attorney general and local prosecuting attorneys shall cooperate with**  
26 **the bureau in the submission and collection of the information necessary for inclusion in**  
27 **the report; and**

28           **(5) Any recommendations regarding continuance of and improvements in the pilot**  
29 **project.**

30

31 **Nothing in this section shall be construed as authorizing the inclusion or release of any**  
32 **identifying information of any reporter or person who is identified as a person who is**  
33 **attempting to fraudulently obtain prescription controlled substances.**

34           **3. Any person who in good faith reports to the bureau under this section shall be**  
35 **immune from any civil or criminal liability as the result of such good faith reporting.**

36           **4. The department of health and senior services may promulgate rules to implement**  
37 **the provisions of this section. Any rule or portion of a rule, as that term is defined in**  
38 **section 536.010, that is created under the authority delegated in this section shall become**  
39 **effective only if it complies with and is subject to all of the provisions of chapter 536 and,**  
40 **if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any**  
41 **of the powers vested with the general assembly pursuant to chapter 536 to review, to delay**  
42 **the effective date, or to disapprove and annul a rule are subsequently held**  
43 **unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted**  
44 **after August 28, 2015, shall be invalid and void.**

45           **5. The department shall implement and provide all monitoring under the pilot**  
46 **project with existing department employees. Nothing in this section shall be construed as**  
47 **authorizing the hiring of additional employees to implement this pilot project, and the**  
48 **department is required to implement this pilot project upon receipt of gifts, grants, and**  
49 **donations received for such purpose, without any additional state appropriations or**  
50 **department staff; except that, the department may enter into agreements with other state**  
51 **agencies or a private vendor, as necessary, to ensure the effective operations of the**  
52 **program if such agreements are funded solely from gifts, grants, and donations. Any**  
53 **agency or private vendor entering into an agreement with the department for the pilot**  
54 **project shall comply with the confidentiality provisions regarding the prescription**  
55 **information under section 195.456.**

56           **6. Under section 23.253 of the Missouri sunset act:**

57           **(1) The provisions of the new program authorized under this section shall**  
58 **automatically sunset three years after the effective date of this section unless reauthorized**  
59 **by an act of the general assembly;**

60           **(2) If such program is reauthorized, the program authorized under this section**  
61 **shall automatically sunset twelve years after the effective date of the reauthorization of this**  
62 **section; and**

63           **(3) This section shall terminate on September first of the calendar year immediately**  
64 **following the calendar year in which the program authorized under this section is sunset.**

Section B. Section A of this act is hereby submitted to the qualified voters of this state  
2 for approval or rejection at an election which is hereby ordered and which shall be held and  
3 conducted on the Tuesday immediately following the first Monday in November, 2016, or at a  
4 special election to be called by the governor for that purpose, pursuant to the laws and  
5 constitutional provisions of this state applicable to general elections and the submission of



6 referendum measures by initiative petition, and it shall become effective when approved by a  
7 majority of the votes cast thereon at such election and not otherwise.

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